SEP 2 8 2000

K002452

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Date:	August 3, 2000
Trade Name:	3M™ RelyX™ Veneer Cement Try-In Paste
Common Names:	Veneer Cement Try-In Paste
Classification Names:	Dental Cement 21 CFR §872.3275 Class II
Predicate devices:	Insure™ Prevue™ Try-In Gels

The 3M™ RelyX™ Veneer Cement Try-In Paste is a pigmented, water soluble try-in paste that is used to determine the appropriate corresponding shade of resin cement needed to bond porcelain or composite veneers. This device is based on the water-soluble polymer, polyethylene glycol. Similar predicate devices utilize glycerin as their water-soluble polymer. The polyethylene glycol performs and behaves in a similar manner as the glycerin and provides for improved viscosity properties.

The 3M™ RelyX™ Veneer Cement Try-In Paste is used in conjunction with the resin cement as a system for bonding porcelain and composite veneers. The try-in paste and predicate device are pigmented specifically to match the corresponding shade of the resin cement. The try-in paste and predicate device are applied to the inside surface of the veneer and placed on the tooth to determine color matching. If the color match is acceptable, the veneer is removed and the try-in paste is completely rinsed off of the tooth and veneer with a water spray. The try-in paste does not leave a residue. Once the appropriate shade has been determined and the try-in paste has been removed, the veneer is permanently cemented in place utilizing a separate adhesive and resin cement. The predicate device is used in the same manner

The 3M™ RelyX™ Veneer Cement Try-In Paste has similar technological characteristics as the predicate device. The specific characteristics that the try-in paste and predicate device share are similar consistency values, complete water solubility leaving no residue, and pigmented shades that match the corresponding cured resin cement.

Based on the conclusions drawn from the safety analysis conducted for this device and the results of the bench testing, 3M™ RelyX™ Veneer Cement Try-In Paste is safe, effective and performs as well or better than the predicate device mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2000

Ms. Shannon Pettit
Regulatory Affairs Associate
Dental Products Laboratory
3M Center, Building 260-2B-09
Saint Paul, Minnesota 55144-1000

Re: K002452
Trade Name: 3M Rely X Veneer Cement Try-In Paste
Regulatory Class: II
Product Code: EMA
Dated: August 3, 2000
Received: August 10, 2000

Dear Ms. Pettit:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002452

Device Name: 3M™ RelyX™ Veneer Cement Try-In Paste

Indications for Use:

3M™ RelyX™ Veneer Cement Try-In Paste is a non-reacting color matching material for use in evaluating veneer appearance prior to permanent cementation of the veneer. 3M™ RelyX™ Veneer Cement Try-In Paste facilitates a close visual approximation of the final aesthetics of the bonded outcome, but in a water-soluble removable manner.

(Please do not write below this line - Continue on another page if needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002452